

OBJECTIVES: Pressure ulcers (PU) are distressing events, caused when skin and the underlying tissues are placed under pressure sufficient to impair blood supply. They can have a substantial impact on quality of life, and have significant resource implications, with extended hospital stays and significant staff time devoted to treating the more severe cases. Repositioning is a key prevention strategy, but can be resource intensive, leading to variation in practice. This economic analysis formed part of the National Institute for Health and Care Excellence (NICE) clinical guideline on PU prevention and management, and was conducted to identify the most cost-effective repositioning strategy for the prevention of PU. **METHODS:** The clinical inputs to the model were taken from the systematic review of clinical data conducted for the guideline. The model population was elderly people in a nursing home; this represents a group at high risk of developing a PU. The economic model was developed in consultation with members of the guideline development group (GDG), and took the perspective of the UK National Health Service. Outcomes were expressed as costs and quality adjusted life years (QALYs). **RESULTS:** Despite being marginally more clinically effective, 2 and 4 hourly repositioning is not cost-effective (compared to 4 hourly repositioning) for this high risk group of patients at a cost-effectiveness threshold of £20,000 per QALY. The ICER was £1,854,070 per QALY. **CONCLUSIONS:** 2 and 4 hourly repositioning is not cost-effective (compared to 4 hourly repositioning) in the UK for the group of patients analyzed here. These results were used to inform the guideline recommendations. **FUNDING:** This work was undertaken by the National Clinical Guideline Centre, which received funding from NICE. The views expressed in this publication are those of the authors and not necessarily of the institute.

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AN ECONOMIC EVALUATION OF RANIBIZUMAB VERSUS AFLIBERCEPT FOR THE TREATMENT OF NEOVASCULAR (WET) AMD IN THE UNITED KINGDOM

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OBJECTIVES: To evaluate the cost-effectiveness of ranibizumab compared with aflibercept for the treatment of neovascular (wet) age-related macular degeneration AMD from the UK healthcare provider perspective. **METHODS:** A patient simulation model was developed with best corrected visual acuity (BCVA) used as a marker of disease progression. Baseline patient characteristics were based on the EXCITE Phase III study. Change in BCVA for Year 1 and Year 2 were based on a network meta-analysis. Beyond Year 2 or after treatment discontinuation, BCVA in the treated eye was modelled using natural history data for wet AMD patients. Natural history data for the general population was used to model the untreated eye. BCVA change in each eye was modelled independently. A probability of developing bilateral disease was applied throughout the model. Utility values were estimated by a regression analysis of BCVA in the better-seeing eye (BSE) and in the worse-seeing eye (WSE). Three scenarios based on different treatment and monitoring schedules were analyzed; pro-re-nata (PRN), treat and extend (T&E), observe and extend (O&E). The model assumed that 50% of patients were treated via one-stop monitoring, and 50% with two-stop monitoring. **RESULTS:** The difference in lifetime costs associated with ranibizumab (0.5mg) ranges from a saving of £22 with T&E regimen, to a reduction of £7,416 with a PRN regimen. In addition, ranibizumab was associated with lifetime quality-adjusted life years (QALYs) of 5.07 compared with 5.06 for aflibercept and as a consequence dominated aflibercept. Probabilistic sensitivity analysis suggests that the probability of ranibizumab (0.5mg) being cost-effective with a T&E regimen is 27% at a £20,000 threshold, and 30% at a £30,000 threshold. With a PRN regimen, the probability of cost-effectiveness was 86% at a £20,000 threshold and 86% at a £30,000 threshold. **CONCLUSIONS:** Ranibizumab dominates aflibercept for patients with neovascular AMD irrespective of treatment regimen.

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ESTIMATING COST-EFFECTIVE DEVICE PRICES FOR PEDIATRIC COCHLEAR IMPLANTATION IN INDIA

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OBJECTIVES: The World Health Organization reports that India's rates of debilitating hearing loss are more than double rates in Europe and North America. With a population over 1.25 billion, India's burden of hearing loss is extremely high. The cochlear implant (CI) is a highly effective treatment, providing some hearing to the deaf, however, CI use is extremely limited in India due to device cost, low incomes, limited medical and audiology expertise, and lack of awareness. The objective of this study is to estimate the cost of a CI device whose use would be considered cost-effective in India for 1-year old children—the subgroup with the greatest utility gain. **METHODS:** The lifetime QALYs gained and payer costs are estimated based on a literature review and Indian life tables, and are discounted at 3% annually. The threshold incremental cost-utility ratio (ICUR) is considered at 3x, 2x, and 1x per capita gross domestic product (PCGDP). Given cost estimates of pre-implant evaluations, surgery costs, post-implant audiology care, device upkeep, and the medical costs of complications and revision surgery, the ICUR equation is solved to determine the maximum cost-effective device cost. **RESULTS:** The health utility gain for a CI device implanted in a 1-year old was estimated at 0.36 with confidence interval (0.29; 0.43). Lifetime QALY gain was 9.28 (7.47; 11.03). Lifetime costs excluding the device cost were \$14,895 (\$10,639–\$20,853). Given a PCGDP of \$1,666, the cost-effectiveness willingness-to-pay thresholds for maximum device cost for 3x, 2x and 1x PCGDP were \$24,664 (\$10,973; \$36,664), \$11,477 (\$36; \$20,896) and -\$1,709 (-\$10,242; \$5,129), respectively. The current minimum price of the device is ~\$12,000. **CONCLUSIONS:** CIs in 1-year olds would be cost-effective in India based on a threshold of 3x or 2x PCGDP, but medical and device costs would have to be reduced to meet a 1x PCGDP threshold.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

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DIAGNOSTIC DELAY IN PATIENTS DIAGNOSED WITH CUTANEOUS MALIGNANT MELANOMA

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OBJECTIVES: The aim of the present study was to assess the diagnostic delay and the associated factors in patients with cutaneous malignant melanoma. **METHODS:** We carried out a survey including medical record analysis in patients diagnosed within five years with cutaneous malignant melanoma at the Pécs Dermatological Clinic (n=362). The study investigated the diagnostic delay, its risk factors as clinical and histological characteristics of the tumor, and patients' sociodemographic factors. Chi-square test, Mann-Whitney U test, and Kruskal-Wallis test was used with 95% probability level (p<0.05). **RESULTS:** 195 females and 167 males participated in the investigation. The mean age was 54.5+/-14.8. Breslow tumor thickness was below 1 mm in 48.1% of patients and above 4 mm in 12.2% of patients. 35.1% of patients consulted a doctors six or more months later than the symptoms had appeared. The mean delay was 8.1+/-15.6 months. The prolonged delay resulted in more expressed tumor thickness (p=0.027). Tumor thickness and delay showed no significant difference in the case of the tumor type and ulceration (p>0.05). A higher proportion of women discovered the abnormality compared with men (65.2% versus 34.8%; p<0.001). The latter subjects were informed by their relatives to examine themselves. The most common site of prevalence was the lower limb in females (78.5% of cases); the trunk in males (61.3% of cases) (p<0.001). The most common symptom observed by patients was the increase in lesion size (50.3%). Its prevalence on the lower limb (p=0.01) and the increase in lesion size (p<0.001) was associated with significantly longer delay. **CONCLUSIONS:** The study provides essential information for developing education campaigns in the future involving awareness promotion related to lesions perceived as minor significance. The present study emphasizes the importance of mindfulness and skills in the early detection of tumors. Prevention should be a decisive factor in primary care.

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MEASUREMENT PROPERTIES OF THE PATIENT-REPORTED PSORIASIS SYMPTOM INVENTORY DAILY DIARY IN PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

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OBJECTIVES: To evaluate measurement properties of the Psoriasis Symptom Inventory (PSI) in moderate/severe plaque psoriasis (PsO). **METHODS:** A secondary analysis of pooled data from a Phase III study of brodalumab in moderate to severe PsO patients (n=661) was conducted. Outcome measures included: PSI (as a daily electronic diary), Psoriasis Area and Severity Index (PASI), static Psoriasis Global Assessment (sPGA), involved body surface area (BSA), Dermatology Life Quality Index (DLQI), and the 36-item Health Survey version 2 (SF-36v2). Analyses included: confirmatory factor analysis (CFA) and Rasch analysis (dimensionality and item performance); Cronbach's α (internal consistency); intraclass correlation coefficients (ICCs) among patients with stable disease (test-retest reliability); Spearman correlations (convergent validity); analysis of variance (known groups validity and ability to detect change); and agreement (Kappa, k) between PSI responders (PSI total score ≤ 8 with no item score > 1) and PASI 75/90, sPGA 0/1, and DLQI 0/1 responders. **RESULTS:** Results supported unidimensionality, good item fit, ordered responses, and combining of items into a single total score. Cronbach's α s were ≥ 0.92 at baseline. Test-retest ICCs were ≥ 0.95 (week 6 to 8). At baseline, moderate/strong correlations between PSI total score and DLQI item 1 (skin symptoms; $r=0.69$), DLQI symptoms and feelings domain ($r=0.66$), and SF-36 bodily pain ($r=-0.58$) supported convergent validity. PSI scores were significantly different (p<0.001) among known PsO severity groups based on PASI (<12 or ≥ 12), sPGA (0-1, 2-3, or 4-5), BSA (<5, 5-10, or > 10), and DLQI (≤ 5 or > 5) at week 8 and 12. At week 12, the PSI detected significant changes in PsO severity based on PASI (<50; 50<75; ≥ 75) and sPGA (0/1; ≥ 2), and showed good agreement ($k \geq 0.66$) between PSI response and PASI, sPGA, and DLQI responses. **CONCLUSIONS:** The PSI demonstrated excellent reliability, validity, and ability to detect change in severity of psoriasis signs and symptoms.

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MEASURING DISEASE SPECIFIC IMPACT AND SYMPTOMS AMONG PATIENTS WITH HIDRADENITIS SUPPURATIVA

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OBJECTIVES: Patients with Hidradenitis Suppurativa (HS) experience painful abscesses and nodules primarily in the skin flexures, along with other disease-related impact and symptoms, which can further diminish their health-related quality of life. No HS-specific tools exist to assess those symptoms and impacts. We aimed to report the development and initial psychometric evaluation of the Hidradenitis Suppurativa Symptom Assessment (HSSA) and the Hidradenitis Suppurativa Impact Assessment (HSIA). **METHODS:** The HSSA and HSIA were developed based on a literature review and concept elicitation interviews with HS patients (n=20). Following initial construction, the questionnaires were cognitively debriefed among HS patients (n=20) to test their readability and comprehensiveness. Next, the HSIA and HSSA were implemented in a multi-center, non-interventional study with HS patients (n=40) to evaluate their item and scale